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TITLE: Resistant Behaviors by People with Alzheimer Dementia and Traumatic Brain Injury

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

This project intends to determine whether distance-accessible real time caregiver coaching is associated with improved caregiver burden and quality of life among people providing care to individuals with behavioral and psychiatric symptoms of dementia or neuropsychiatric symptoms after traumatic brain injury. Development of caregiver training materials and intervention strategies occurred as planned and on schedule. Enrollment of participants began close to the original schedule and is ongoing. Potential barriers to recruitment, including the definition of "care resistant behavior" have been addressed and appear to have resolved a slow start to enrollment. Important qualitative observations about the intervention and participant responses have been derived by the intervention team and these are being considered for scholarly reporting and publication. An insufficient number of participants has completed the information for the research team to have collected quantitative data on caregiver burden and family quality of life for statistical analysis. This is consistent with our work plan and expectations for year 1. The project remains active and on schedule.

15. SUBJECT TERMS Dementia – Traumatic Brain Injury – Caregiving – Caregiver Burden – Quality of Life					
16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON** USAMRMC
a. REPORT U	**b. ABSTRACT** U	**c. THIS PAGE** U	UU	16	**19b. TELEPHONE NUMBER** *(include area code)*

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INTRODUCTION

This research addresses whether theoretically-driven caregiver education and coaching in non-pharmacologic approaches to reduce care resistant behaviors as a trigger of behavioral and psychiatric symptoms of dementia (BPSD) and neuropsychiatric symptoms after Traumatic Brain Injury (NPTBI) will improve caregiver burden and improve quality of life (QOL) for patients and their families. This project will use the innovative approach of distance learning (DL) methods to **teach** caregivers of people with BPSD and NPTBI theoretically determined behavioral techniques and **coach** them on strategies to reduce those adverse behaviors. The combined qualitative, quantitative, and economic analyses will also provide pertinent information regarding the general acceptance, utility, reproducibility, and transferability of NeuroNS-Care to larger groups of family caregivers. These will help guide strategy for the near-certain implementation of synchronous and asynchronous caregiver training programs for both AD and TBI. The proposed study also has the potential to inform healthcare policy and practice for family caregivers of persons with dementia or recovering from TBI.

2. KEYWORDS: Provide a brief list of keywords (limit to 20 words).

Dementia – Traumatic Brain Injury – Caregiving – Caregiver Burden – Quality of Life

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Specific Aims:

1. Translate a theoretically-driven intervention, demonstrated to be effective to reduce care resistant behaviors among nursing home resident with dementia to a distance-learning education, training, and coaching program for family caregivers of people with dementia or TBI.
2. Assess the efficacy of the intervention for reducing frequency or severity of CRB-triggered symptoms of agitation, aggression, and irritability.
3. Assess the efficacy of the intervention for improving quality of life of patients, caregivers, and families
4. Determine how patient and caregiver characteristics influence the effectiveness of the intervention
5. Evaluate how the intervention affects the health care costs of people with dementia or TBI.

Major Task 1: Adapt MOUTh techniques to NeuroNS-Care protocol	Target Month	
Subtask 1: Prepare Regulatory Documents and Research Protocol for Study		
***Milestone Achieved**: Local IRB approval at UAB*	3	Completed 9/9/2016
Milestone: HRPO approval	4	Completed 12/20/2016
Milestone : Educational materials completed and deployed to web site	4	Completed 1/13/2017
Milestone: Educational materials updated and maintained on web	4-36	N/A

Major Task 2: Hire/Train/Maintain Staff for Clinical Trials	**Timeline**	
Subtask1: Hiring and Training of Study Staff		100 complete
Milestone: Research staff trained	4	100% complete
Subtask 2: Facilitate hiring, training, supervision and fidelity checks as needed for attrition	4-36	N/A
Milestone Achieved: Maintained trained and available Independent Evaluators throughout duration of both clinical trials	4-36	N/A
Major Task 3: Randomized Controlled Trial		
Milestone: 1st participant consented, screened and enrolled	5	Completed 3/15/2017
Milestone: Report findings from overall studies	36/post funding	N/A
Major Task 4: Data Analysis		N/A
Milestone: Report results from data analyses	36	N/A

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to Report.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

We plan to continue our recruitment efforts. Regular coaching sessions with Drs. Jablonski and Winstead are ongoing. Team meetings with Drs. Geldmacher and Novak provide feedback and suggestions for the content and direction of coaching sessions in addition to the unsolicited (and useful) feedback provided by caregiver participants.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Important qualitative observations about the intervention and participant responses have been derived by the intervention team and these are being considered for scholarly reporting and publication. These observations may help shape future similar interventions. No reporting of the observations occurred during the reporting period.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report

5. CHANGES/PROBLEMS: The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

· Original issue: Follow-up visits require both caregiver and person with AD/TBI to travel to the original study site(s) in Birmingham, AL. To reduce caregiver burden, we received approval for an amendment to the protocol and consent forms to the local IRB to allow follow-up visits to be done online or by phone if preferred. · An additional amendment was submitted that allowed caregivers in the delayed intervention to access AD and TBI resources immediately after randomization rather than delaying access out six weeks. This was also approved by the local IRB. · Enrollment numbers for AD dyads declined for the fourth quarter. To address this, we have contacted the director of the UAB Geriatric Clinics. This clinic has local IRB approval as an additional recruitment site. They have agreed to provide referrals for AD dyads to the project. We plan to follow-up with them, providing recruitment materials such as brochures and fliers, pending IRB approval. Additionally, some potential referring providers from the Memory Disorders Clinics used a more restrictive definition of care resistant behaviors than the study criteria. This reduced the number of referrals for BPSD participants. That knowledge gap has been addressed.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

. Nothing to Report

Significant changes in use or care of vertebrate animals

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

  Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year*

(international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.

Nothing to Report

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report

- **Other Products**

  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Name	David Geldmacher, MD
Project Role	PI
Research Identifier	orcid.org/0000-0003-2958-1876
Nearest person month worked	2
Contribution to Project:	Dr. Geldmacher provided content and oversight of IRB application, rater training and content development. He chairs investigator meetings, oversees recruitment and study progress, and meets with Drs. Jablonski and Winstead regarding study and intervention operations.
Name	Rita Jablonski-Jaudon, PhD
Project Role	Co-Investigator
Research Identifier	SCOPUS 8616238300
Nearest person month worked	2
Contribution to project	Dr. Jablonski conducted the development and review of educational materials for caregivers in collaboration with co-investigators Dr. Geldmacher and Dr. Novack, with assistance from Dr. Winstead. She conducts the caregiver coaching sessions.
Name	Vicki Winstead
Project Role	Program Manager
Research Identifier	orcid.org/0000-0001-8037-0164
Name	5
Contribution to Project:	Dr. Winstead assisted co-investigator, Dr. Jablonski, in the completion, editing and deployment of educational and training materials for caregiver. She worked with grant personnel in resources site improvement and in providing access to participants. She worked closely with the psychometrician to develop proficiency in participant evaluation. She assisted in finalizing recruitment materials including flyers and scripts. She has participated and continues to participate in caregiver coaching for 9 participants.
Name	Dr. Stephen Mennemeyer
Project Role	Co-investigator
Research Identifier	orcid.org/0000-0002-6039-7965

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Dr. Geldmacher has been appointed site PI of the ADNI-3 study (U19AG024904); M. Weiner;PI. NIH/UCSD/University of Southern California. Assigned effort is 1 calendar months.

Dr. Geldmacher has relinquished Site PI responsibilities for NIA U19AG010483 and Alzheimer's Association/USC clinical trials contract CTALEARN012.

Effort committed to this project has been reduced from 2.40 to 2.04 calendar months annually.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to **https://ers.amedd.army.mil** for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

9. APPENDICES:

Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.